

AMENDMENTS TO THE CLAIMS

5 This list of claims replaces the prior version of claims in the application:

1. (original): A pharmaceutical formulation comprising one or more excipients and 3 α ,16 α ,17 β -trihydroxy-5 α -androstane, 3 α ,16 α -dihydroxy-17-oxo-5 α -androstane, 3 β ,16 α ,17 β -trihydroxy-5 α -androstane, 3 β ,16 α -dihydroxy-

10 17-oxo-5 α -androstane, 3 α ,16 β ,17 β -trihydroxy-5 α -androstane, 3 α ,16 β -dihydroxy-17-oxo-5 α -androstane, 3 α ,16 α ,17 β -trihydroxy-5 β -androstane, 3 α ,16 α -dihydroxy-17-oxo-5 β -androstane, 3 β ,16 α ,17 β -trihydroxy-5 β -androstane, 3 β ,16 α -dihydroxy-17-oxo-5 β -androstane, 3 α ,16 β ,17 β -trihydroxy-5 β -androstane, 3 α ,16 β -dihydroxy-17-oxo-5 β -androstane, 3 β ,16 β -dihydroxy-17-oxo-5 β -androstane or a 2-oxa, 11-oxa or 19-nor analog of any of these compounds.

20 2. (original): The pharmaceutical formulation of claim 1 wherein the compound is 3 α ,16 α ,17 β -trihydroxy-5 α -androstane.

25 3. (original): The pharmaceutical formulation of claim 1 wherein the compound is 3 α ,16 α -dihydroxy-17-oxo-5 α -androstane.

30 4. (original): A pharmaceutical formulation for buccal or sublingual administration comprising one or more excipients and a compound wherein the compound is 16 α -fluoro-17-oxoandrost-5-ene, 3 α -hydroxy-16 α -fluoro-17-oxoandrost-5-ene, 3 β -hydroxy-16 α -fluoro-17-oxoandrost-5-ene 7 α -hydroxy-16 α -fluoro-17-oxoandrost-5-ene, 7 β -hydroxy-16 α -fluoro-17-oxoandrost-5-ene, 16 α -fluoro-7,17-dioxoandrost-5-ene.

5. (original): The pharmaceutical formulation of claim 4 wherein the compound is micronized.

6. (original): The pharmaceutical formulation of claim 4 wherein the
5 compound is 16 α -fluoro-17-oxoandrost-5-ene.

7. (original): A pharmaceutical formulation comprising one or more excipients and two or more of 3 β -hydroxy-16 α -bromo-17-oxo-5 α -androstane, 3 β -hydroxy-16 β -bromo-17-oxo-5 α -androstane and 3 β -hydroxy-16 α -bromo-
10 17-oxo-5 α -androstane hemihydrate.

8. (original): The pharmaceutical formulation of claim 7 wherein the pharmaceutical formulation is for oral, buccal, sublingual or aerosol administration.

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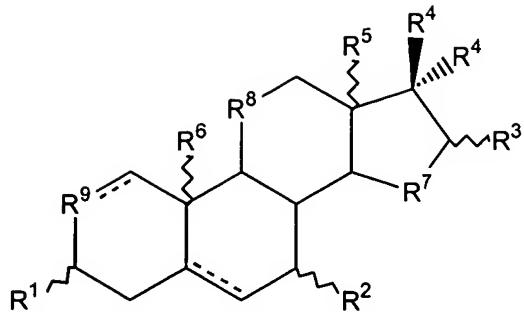
9. (original): The pharmaceutical formulation of claim 7 comprising 7 3 β -hydroxy-16 β -bromo-17-oxo-5 α -androstane and 3 β -hydroxy-16 α -bromo- 17-oxo-5 α -androstane hemihydrate.

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10. (original): The pharmaceutical formulation of claim 9 wherein the pharmaceutical formulation is for oral, buccal, sublingual or aerosol administration.

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11. (original): A method to increase the numbers or activity of neutrophils, dendritic cells, macrophages or monocytes in a human or a primate having or subject to developing an innate immune suppression condition or a symptom thereof comprising administering an effective amount of a compound having the formula



wherein the dotted lines are optional double bonds and when hydrogen is present at the 5-position, it is in the α -configuration;

5 R¹ is -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, -O-Si-(R¹³)₃, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a sulfite ester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, a carbonate, a carbamate, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

10 R² and R³ independently are -H, -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, -O-Si-(R¹³)₃, -CN, =O, =S, =NOH, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a sulfite ester, a sulfate ester, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

15 R⁴ independently are -H, -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, -O-Si-(R¹³)₃, -CN, =O, =S, =NOH, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphinester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, a carbonate, a carbamate, a thioacetal, an alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide or an optionally substituted oligosaccharide, provided that both R⁴ are not -H;

R^5 and R^6 independently are -H, an acyl group, a thioacyl group, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group or an optionally substituted alkynyl group;

R^7 is $-\text{CHR}^{10}-$, $-\text{CHR}^{10}-\text{CHR}^{10}-$, $-\text{CHR}^{10}-\text{CHR}^{10}-\text{CHR}^{10}-$, $-\text{CHR}^{10}-\text{O}-$
5 $\text{CHR}^{10}-$, $-\text{CHR}^{10}-\text{S-CHR}^{10}-$, $-\text{CHR}^{10}-\text{NR}^{\text{PR}}-\text{CHR}^{10}-$, $-\text{O}-$, $-\text{O-CHR}^{10}-$, $-\text{S-}$, $-\text{S-}$
 $\text{CHR}^{10}-$, $-\text{NR}^{\text{PR}}-$ or $-\text{NR}^{\text{PR}}-\text{CHR}^{10}-$, where R^{10} independently are -H, $-\text{OR}^{\text{PR}}-$,
a phosphoester, a phosphothioester, a phosphonoester, a phosphinester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a
10 thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide or optionally substituted
15 oligosaccharide;

R^8 and R^9 independently are $-\text{CHR}^{10}-$, $-\text{CHR}^{10}-\text{CHR}^{10}-$, $-\text{O}-$, $-\text{O-CHR}^{10}-$,
 $-\text{S-}$, $-\text{S-CHR}^{10}-$, $-\text{NR}^{\text{PR}}-$ or $-\text{NR}^{\text{PR}}-\text{CHR}^{10}-$, or R^8 or R^9 independently is absent, leaving a 5-membered ring-, where R^{10} independently are -H, $-\text{N}(\text{R}^{\text{PR}})_2$, $-\text{CN}$, $=\text{NOH}$, $=\text{CH}_2$, an amide, an acyl group, a thioacyl group, a halogen, an
20 optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety or an optionally substituted heteroaryl moiety;

R^{13} independently are C_{1-6} alkyl; and

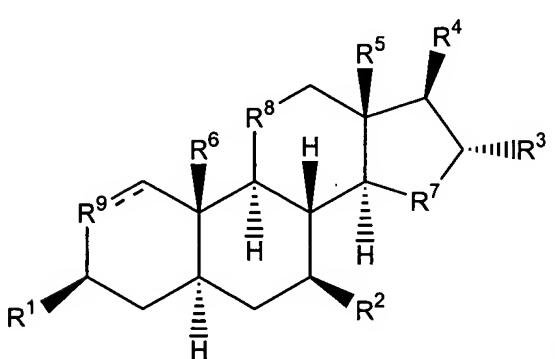
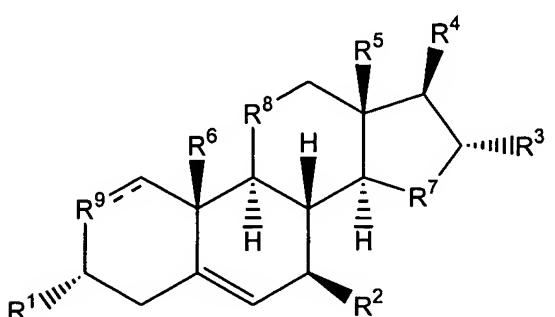
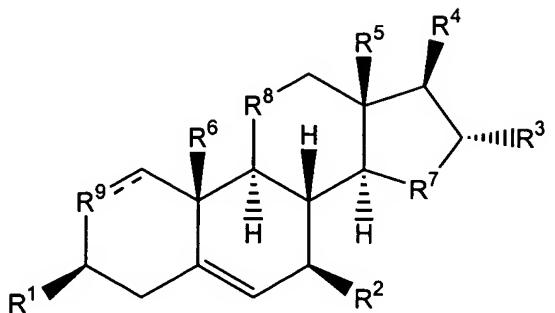
R^{PR} independently are -H or a protecting group.

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12. (original): The method of claim 11 wherein about 4 to about 40 mg/kg/day, of the compound is administered to the human or the primate.

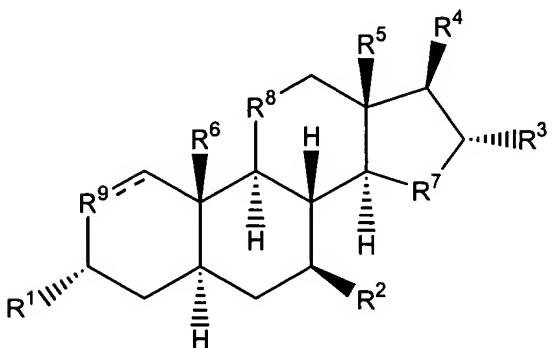
30 13. (original): The method of claim 12 wherein the compound is intermittently administered to the subject.

14. (original): The method of claim 11 wherein the compound has the formula



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or



15. (original): The method of claim 14 wherein

(1) R^1 and R^4 are -OH, R^2 and R^3 are -H, R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

(2) R^1 and R^4 are -OH, R^2 is -H, R^3 is -F, -Cl, -Br or -I, R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

5 (3) R^1 , R^2 and R^4 are -OH, R^3 is -H, R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

(4) R^1 , R^2 and R^4 are -OH, R^3 is -F, -Cl, -Br or -I R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

10 (5) R^1 is -OH, R^2 is -H, R^3 is -OH, -F or -Br, R^4 is =O, R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

(6) R^1 and R^2 are -OH, R^3 is -H, -F, -Cl or -Br, R^4 is =O, R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

(7) R^1 , R^3 and R^4 are -OH, R^2 is -H, R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

15 (8) R^1 , R^2 , R^3 and R^4 are -OH, R^5 and R^6 are -CH₃ and R^7 , R^8 and R^9 are -CH₂-; or

(9) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are -H, R^5 is -CH₃, R^7 , R^8 and R^9 are -CH₂-; or

20 (10) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -Br, R^5 is -CH₃, R^7 , R^8 and R^9 are -CH₂-; or

(11) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -OH, R^5 is -CH₃, R^7 , R^8 and R^9 are -CH₂-; or

25 (12) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -OH, R^5 is -CH₃, R^7 , R^8 and R^9 are -CH₂-; or

(13) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are -OH, R^5 is -CH₃, R^7 , R^8 and R^9 are -CH₂-; or

30 (14) R^1 and R^4 independently are -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are -OH, R^5 is -CH₃, R^7 , R^8 and R^9 are -CH₂-; or

(14) R^1 and R^4 independently are $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is $-OH$, R^3 is $-H$, $-F$, $-Cl$ or $-Br$, R^5 is $-CH_3$, R^7 , R^8 and R^9 are $-CH_2-$; or

5 (15) R^1 is $-H$, R^2 is $-OH$ or $=O$, R^3 is $-OH$, $-F$, $-Cl$ or $-Br$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^5 is $-CH_3$, R^7 , R^8 and R^9 are $-CH_2-$; or

(16) R^1 and R^2 are $-H$, R^3 is $-OH$ or $=O$, $-F$, $-Cl$ or $-Br$, R^4 is $-OR^{PR}$, $-SR^{PR}$, $-N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, 10 a carbonate or a carbamate, R^5 is $-CH_3$, R^7 , R^8 and R^9 are $-CH_2-$; or

(17) any of (1) through (16) above wherein R^9 is $-O-$ or $-NH-$ instead of $-CH_2-$ or $-CH=$; or

(18) any of (1) through (17) above wherein R^8 is $-O-$ or $-NH-$ instead of $-CH_2-$; or

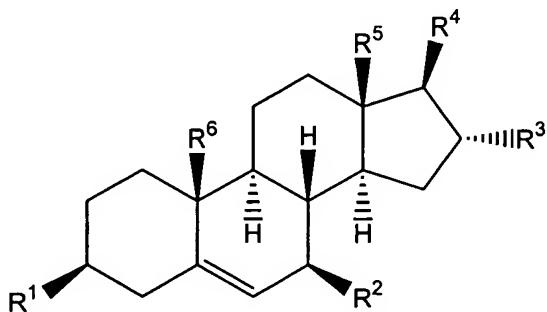
15 (19) any of (1) through (18) above wherein R^7 is $-O-$, $-NH-$ or $-CHR^{10}-$ CH_2 -instead of $-CH_2-$.

16. (original): The method of claim 15 wherein about 4 to about 40 mg/kg/day, of the compound is administered to the human or the primate.

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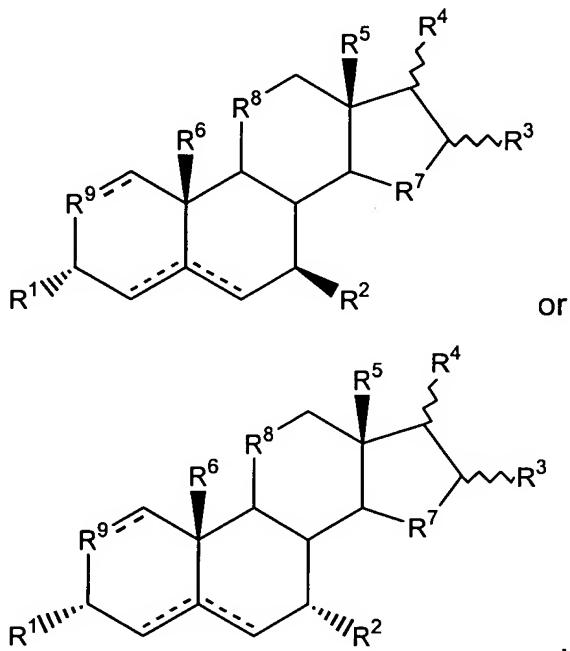
17. (original): The method of claim 16 wherein the compound is intermittently administered to the subject.

25 18. (currently amended): The method of claim 17 wherein the compound ~~compound~~ has the formula



wherein R¹ and R⁴ are -OH, R² and R³ are -H and R⁵ and R⁶ are -CH₃.

19. (original): A method to treat a condition selected from the group consisting of inflammation, osteoporosis, a bone fracture, a wound or trauma
5 and a burn in a human or a primate having, or subject to developing the condition, wherein the compound has the structure

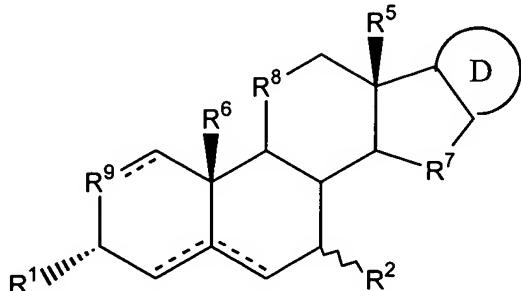


wherein,

10 R¹, R², R³, R⁴, R⁵ and R¹⁰ independently are -H, -OR^{PR}, -SR^{PR}, -N(R^{PR})₂, -N₃, -O-Si-(R¹³)₃, -CN, -NO₂, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, an optionally substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group, an optionally substituted aryl moiety, an optionally substituted heteroaryl moiety, an optionally substituted monosaccharide, an optionally substituted oligosaccharide, or,
15 one more of R², R³ and R¹⁰ independently are =O, =S, =NOH or =CH₂, or,
20 one more of R², R³ and R¹⁰ independently are =O, =S, =NOH or =CH₂,

R^4 is $=O$, $=S$ or $=NOH$, or,

R^3 and both R^4 together comprise a structure having the formula



R^6 is $-H$;

5 R^7 is $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$, $-CHR^{10}-CHR^{10}-CHR^{10}-$, $-CHR^{10}-O-$
 $CHR^{10}-$, $-CHR^{10}-S-CHR^{10}-$, $-CHR^{10}-NR^{PR}-CHR^{10}-$, $-O-$, $-O-CHR^{10}-$, $-S-$, $-S-$
 $CHR^{10}-$, $-NR^{PR}-$ or $-NR^{PR}-CHR^{10}-$;

10 R^8 and R^9 independently are $-CHR^{10}-$, $-CHR^{10}-CHR^{10}-$, $-O-$, $-O-CHR^{10}-$,
 $-S-$, $-S-CHR^{10}-$, $-NR^{PR}-$ or $-NR^{PR}-CHR^{10}-$, or R^8 or R^9 independently is absent,

15 leaving a 5-membered ring;

R^{13} independently is C_{1-6} alkyl;

R^{PR} independently are $-H$ or a protecting group;

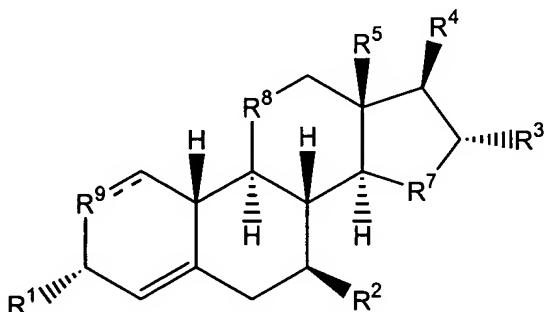
20 D is a heterocycle or a 4-, 5-, 6- or 7-membered ring that comprises
saturated carbon atoms, wherein 1, 2 or 3 ring carbon atoms of the 4-, 5-, 6-
or 7-membered ring are optionally independently substituted with $-O-$, $-S-$ or $-$
 $NR^{PR}-$ or where 1, 2 or 3 hydrogen atoms of the heterocycle or where 1 or 2
hydrogen atoms of the 4-, 5-, 6- or 7-membered ring are substituted with -
 OR^{PR} , $-SR^{PR}$, $-N(R^{PR})_2$, $-O-Si-(R^{13})_3$, $-CN$, $-NO_2$, an ester, a thioester, a
phosphoester, a phosphothioester, a phosphonoester, a phosphinester, a
sulfite ester, a sulfate ester, an amide, an amino acid, a peptide, an ether, a
thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a
thioacetal, a halogen, an optionally substituted alkyl group, an optionally
substituted alkenyl group, an optionally substituted alkynyl group, an
optionally substituted aryl moiety, an optionally substituted heteroaryl moiety,
25 an optionally substituted monosaccharide, an optionally substituted

oligosaccharide, a nucleoside, a nucleotide, an oligonucleotide or a polymer, or,

one more of the ring carbons are substituted with =O, =S, =NOH, =NOC(O)CH₃ or =CH₂,

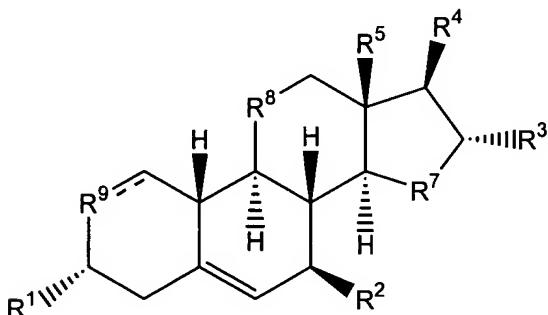
5 or D comprises two 5- or 6-membered rings, wherein the rings are fused or are linked by 1 or 2 bonds.

21. 20. (currently amended): The method of claim 20-19 wherein the compound has the structure



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or



21. (original): The method of claim 20 wherein
(1) R¹ and R⁴ are -OH, R² and R³ are -H, R⁵ is -CH₃, R⁷, R⁸ and R⁹ are
15 -CH₂-; or
(2) R¹ and R⁴ are -OH, R² is -H, R³ is -Br, R⁵ is -CH₃, R⁷, R⁸ and R⁹ are
-CH₂-; or
(3) R¹ and R⁴ are -OH, R² is -H, R³ is -F, R⁵ is -CH₃, R⁷, R⁸ and R⁹ are
-CH₂-; or
20 (4) R¹, R² and R⁴ are -OH, R³ is -H, R⁵ is -CH₃, R⁷, R⁸ and R⁹ are -
CH₂-; or

(5) R^1 , R^2 and R^4 are -OH, R^3 is -Br, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(6) R^1 , R^2 and R^4 are -OH, R^3 is -F, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

5 (7) R^1 , R^3 and R^4 are -OH, R^2 is -H, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(8) R^1 , R^2 , R^3 and R^4 are -OH, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

10 (9) R^1 and R^4 independently are - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are -H, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(10) R^1 and R^4 independently are - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -Br, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(11) R^1 and R^4 independently are - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a

15 thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -F, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(12) R^1 and R^4 independently are - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 is -H, R^3 is -OH, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

20 (13) R^1 and R^4 independently are - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^2 and R^3 are -OH, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(14) R^1 and R^4 independently are - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a

25 carbamate, R^2 is -OH, R^3 is -H, -F, -Cl or -Br, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(15) R^1 is -H, R^2 is -OH or =O, R^3 is -OH, -F, -Cl or -Br, R^4 is - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

(16) R^1 and R^2 are -H, R^3 is -OH or =O, -F, -Cl or -Br, R^4 is - OR^{PR} , - SR^{PR} , - $N(R^{PR})_2$, an ester, a thioester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R^5 is - CH_3 , R^7 , R^8 and R^9 are - CH_2 -; or

5 (17) any of (1) through (16) above wherein R^9 is -O- or -NH- instead of - CH_2 - or - $CH=$; or

(18) any of (1) through (17) above wherein R^8 is -O- or -NH- instead of - CH_2 -; or

(19) any of (1) through (18) above wherein R^7 is -O-, -NH- or - CHR^{10} - CH_2 - instead of - CH_2 -.

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22. (original): The method of claim 20 wherein the condition is osteoporosis or a bone fracture and the compound is $3\alpha,17\beta$ -dihydroxy-19-norandrost-4-ene or $3\alpha,17\beta$ -dihydroxy-19-norandrost-5-ene.